

Safety Alerts Weekly Update

التقرير الأسبوعي لإنذارات السلامة

Report Reference: WU2542
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الرقم المرجعي للتقرير:
تاريخ النشر:

below is the weekly report of Safety Alerts for the period:

فيما يلي التقرير الأسبوعي لإنذارات السلامة للفترة:

From 05-Oct-25
To 11-Oct-25

من
إلى

which affect Saudi Arabia and being followed up with the authorised representatives to accomplish the required action.

والمتأثرة بها المملكة والتي جاري متابعتها مع الممثلين المعتمدين لإتمام تنفيذ الإجراءات التصحيحية.

* Kindly respond to the weekly report in both cases either you are affected or not affected though the following link:

* نأمل الرد على التقرير الأسبوعي في حالتي التأثر أو عدم التأثر وذلك من خلال الرابط أدناه:

<https://surveys.sfda.gov.sa/surveys/?s=4MT7LEJ3DFP7H8LJ>



* Role of contact officer:

* مسؤولية ضابط الاتصال:

- Disseminate and share the information with other departments within the healthcare facility and ensure that the healthcare facility is free of any affected device/product.
- Communicate with the Authorised Representative of the manufacturer if there is any device/product affected by a Safety Alert
- To identify the affected serial numbers/lots, please open the Safety link.

- التعميم على الإدارات / الأقسام المختلفة داخل المنشأة الصحية والتأكد من خلوها من أي جهاز/مستلزم طبي متأثر بأي من إنذارات السلامة.
- التواصل مع الممثل المعتمد للمصنع في حالة وجود جهاز/مستلزم طبي متأثر بأي من إنذارات السلامة.
- لمعرفة تفاصيل الأجهزة والمستلزمات الطبية المتأثرة، الرجاء فتح رابط إنذار السلامة:

No. of Safety Alerts: 12 عدد إنذارات السلامة

Safety Alert No.	NCMDR Ref.	Medical Device	Manufacturer	Authorized Representative /Importer	Link	Medical Device Category
1	SA-02-10-25-1079	Medistim MiraQ Systems	Medistim ASA	Gulf Medical Co.	https://ade.sfda.gov.sa/Fsca/PublishD	Diagnostic and therapeutic radiation devices
2	SA-02-10-25-1078	Ceiling Suspension Motorized (CSM) of Philips Diagnostic X-Ray (DXR) systems	Philips Medical Systems	Philips Healthcare Saudi Arabia Ltd.	https://ade.sfda.gov.sa/Fsca/PublishD	Diagnostic and therapeutic radiation devices
3	SA-06-10-25-1081	BD BACTEC™ MGIT™ 960 Streptomycin 4.0 Kit	Becton Dickinson & Co. (BD)	Becton Dickinson B.V.	https://ade.sfda.gov.sa/Fsca/PublishD	In vitro diagnostic devices
4	SA-06-10-25-1080	Evidence Investigator Analyser	Randox Laboratories Ltd.	Bio Standards	https://ade.sfda.gov.sa/Fsca/PublishD	In vitro diagnostic devices
5	SA-06-10-25-1083	- RX Daytona + with ISE - RX Daytona + without ISE - RX Imola - RX Modena	Randox Laboratories Ltd.	Bio Standards	https://ade.sfda.gov.sa/Fsca/PublishDetails/575	In vitro diagnostic devices
6	SA-06-10-25-1082	RX Monaco	Randox Laboratories Ltd.	Bio Standards	https://ade.sfda.gov.sa/Fsca/PublishD	In vitro diagnostic devices
7	SA-02-10-25-1077	AVVIGO+ Multi-Modality Guidance System	Boston Scientific Corp..	Boston Scientific Gulf for trading LLC	https://ade.sfda.gov.sa/Fsca/PublishD	Electro mechanical medical devices
8	SA-08-10-25-1087	FreeGo Enteral Feeding set	Abbott Ireland Diagnostics Division	Abbott Saudi Arabia for Trading	https://ade.sfda.gov.sa/Fsca/PublishD	Single-use devices

Safety Alert No.	NCMDR Ref.	Medical Device	Manufacturer	Authorized Representative /Importer	Link	Medical Device Category
9	SA-28-09-25-1069	CODMAN® Disposable Perforator 11mm (26-1222) CODMAN® Disposable Perforator 9mm (26-1223)	Integra LifeSciences Production Corporation	FAROUK, MAAMOUN TAMER & COMPANY	https://ade.sfda.gov.sa/Fsca/PublishDetails/570	Single-use devices
10	SA-09-04-25-846	IntelliSpace Cardiovascular	Philips Medical Systems Nederland B.V.	Philips Healthcare Saudi Arabia Ltd.	https://ade.sfda.gov.sa/Fsca/PublishDetails/172	Medical software
11	SA-07-10-25-1085	Salem Sump™	Cardinal Health 200, LLC..	Medical Regulations Gate	https://ade.sfda.gov.sa/Fsca/PublishDetails/172	Single-use devices
12	SA-04-11-24-656	BD BACTEC™ Blood Culture System BD Phoenix™ M50 Automated Microbiology System BD MAX™ System BD COR™ System BD EpiCenter™ Microbiology Data Management System BD Synapsys™ Informatics Solution	Becton Dickinson & Co. (BD)	Becton Dickinson B.V.	https://ade.sfda.gov.sa/Fsca/PublishDetails/172	In vitro diagnostic devices